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10/587,477	07/26/2006	Hilda Batsheva Ten Brink	F7761(V)	5194

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EXAMINER

FERNANDEZ, SUSAN EMILY

ART UNIT	PAPER NUMBER
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1651

NOTIFICATION DATE	DELIVERY MODE
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03/17/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/587,477	Applicant(s) TEN BRINK ET AL.	
	Examiner SUSAN E. FERNANDEZ	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☒ Claim(s) 1-16 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>9/17/07</u> . | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

The preliminary amendment filed July 26, 2007, has been received and entered.

Claims 1-16 are pending and examined on the merits.

Claim Objections

Claims 1-16 are objected to because of the following informalities: Each of claims 2-10 should begin with the recitation "The process," and each of claims 12-14 should begin with the recitation "The triglyceride." Furthermore, "products" in claim 16 should be replaced with "product." Also, the recitation "Thermomyces lanuginosa" should be italicized in claims 1 and 15. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 15 provides for the use of an aggregate of Thermomyces lanuginose lipase and silica as catalyst for partially rearranging fatty acid residues of a triglyceride fat, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

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Claims 2-5 and 7-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 2-5, 7-11, and 13-15, the phrases "preferably" and "more preferably" render the claims indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). Thus, claims 2-5 and 7-15 are rejected under 35 U.S.C. 112, second paragraph.

Claim 4 is indefinite since it is unclear that the use of the batch reactor is involved with the exposure step recited in parent claim 1.

Claim 5 is indefinite since the recitation of the first hour of conducting oil through a packed bed reactor lacks antecedent basis. First, it is unclear from parent claim 1 that the triglyceride fat is an oil. Furthermore, parent claim 1 does not recite conducting oil through a packed bed reactor. There is no indication that the exposure step of claim 1 entails conducting the triglyceride fat in the form of an oil through a packed bed reactor of the lipase. Claim 5 also recites "the catalyst bed" which lacks antecedent basis. It is unclear that the catalyst bed is of the packed bed reactor.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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Claim 15 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4 and 6-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (US 2003/0054509) in light of Sullivan et al. (US 5,391,383) and Zhang et al. (JAOCS. 2001. 78(1): 57-64. Listed on 9/17/07 IDS).

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Lee et al. discloses contacting a mixture comprising glycerides with lipase to effect esterification or transesterification. See claim 1. In the process, the lipase modifies the physical properties of the glycerides by randomization (page 3, paragraph [0034]). The resulting product can be used in food products such as margarine, shortening, and other confectionary fats (page 7, paragraph [0072]). The mixture treated with the lipase, the initial substrate, can be a mixture of compounds of one or more glycerides (page 1, paragraph [0012]) where the glycerides can be selected from coconut oil, palm oil, triglycerides, and partial or fully hydrogenated oils (page 1, paragraph [0013]). Thus, the initial substrate can be any triglyceride fat which has not been subjected to hydrogenation. According to Sullivan et al., coconut oil is a lauric fat (column 7, line 39), so Lee et al. teaches an initial substrate of a mixture of palm fat and lauric fat when the mixture is of palm oil and coconut oil. Furthermore, the examples of Lee et al. teach an initial substrate of fully hydrogenated soy oil and liquid soy oil (page 8, paragraph [0077] and [0082]). Therefore, Lee et al. also teaches an initial substrate of a mixture of a liquid oil and a hydrogenated oil. In sum, the limitations of instant claims 6 and 12 regarding the specific triglyceride fat.

Example 1 teaches one aspect of the Lee invention, where the Lipozyme TL IM lipase is packed into a column, thus forming a packed bed reactor (page 7, paragraph [0077]). The substrate of a mixture of fully hydrogenated soy oil and liquid soy oil is pumped through the packed bed reactor at a temperature of 65°C for the reaction (page 8, paragraph [0077]). Therefore, the temperature limitation of instant claim 10 is met by Lee et al.

Example 4 teaches the treatment of 400 g of a mixture of fully hydrogenated soy oil and liquid soy oil with 40 g of Lipozyme TL IM lipase at a temperature of 70°C in a batch reactor

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(page 8, paragraph [0082]). The lipase is about 9 wt.% of the reaction mixture (40 g lipase/(400 g oil + 40 g lipase) * 100), thus the catalyst amount limitation in instant claim 4 is met by the reference.

According to Zhang et al., Lipozyme TL IM is an *sn*-1,3-specific lipase from *Thermomyces lanuginosa* with silica granulation (page 561, second column, second-to-last paragraph) which is the preferred lipase for the practice of the instant claimed invention (page 10, lines 10-13). Therefore, the randomization performed by Lee et al. occurs over the terminal and middle positions of the fatty acid residues on the glyceride moiety.

Lee et al. differs from the claimed invention in that it does not teach that the lipase has an activity of at least 250 IUN at the onset of the process. However, the creation of Lipozyme TL IM of different enzyme activities would have been a routine matter of experimentation, as the skilled artisan would have recognized that the properties of the fats/oils produced would have varied according to enzymatic activity. Therefore, the lipase activity level recited in the instant claims would have been rendered obvious.

Lee et al. also does not teach the conversion degree on the terminal positions, Re, and the conversion degree on the middle position, Ra, recited in the instant claims. However, Lee et al. teaches that lipase enzymatic activity is affected by factors such as temperature, light, and moisture content (page 6, paragraph [0060]) and that flow rate, column residence time, and substrate mixture temperature can be adjusted to optimize enzymatic activity (page 7, paragraph [0071]). Given that Lee et al. teaches using the same lipase (Lipozyme TL IM) as used in the instant specification, that the initial enzymatic activity level is rendered obvious (at least 250 IUN), and that various parameters can be altered through routine experimentation to optimize

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lipase enzymatic activity, the conversion degrees of Re and Ra recited in the instant claims would have been rendered obvious. It is a matter of routine optimization and experimentation. As Lee et al. indicates that moisture content affects lipase enzymatic activity, it would have been obvious to have varied the water content, testing various water content levels including that recited in instant claim 9. Thus, claims 1-4 and 10-16 are rendered obvious.

A holding of obviousness is clearly required.

Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al., Sullivan et al., and Zhang et al. as applied to claims 1-4 and 6-16 above, and further in view of Xu et al. (JAOCS. 2002. 79(6): 561-565. Listed on 9/17/07 IDS).

As discussed above, Lee et al., Sullivan et al., and Zhang et al. render claims 1-4 and 6-16 obvious. However, they do not expressly disclose that when the Lee invention is performed in a packed bed reactor of the lipase with the soy oil mixture, the residence time of the the oil in the catalyst bed of the packed bed reactor is less than 25 minutes for the first hour of the process.

Xu et al. discloses obtaining various fat products by the lipase-catalyzed modification of oils and fats (page 561, first paragraph). In the study performed, oil was sent through a packed bed reactor of Lipozyme TL IM (page 561, second column, last two paragraphs). Various flow rates (residence times) were tested to determine their effect on the degree of reaction and the product (page 564, Figure 2). Residence times that were tested ranged from about 5 to about 150 minutes.

At the time the invention was made, it would have been obvious to the person of ordinary skill in the art to have tested various residence times, including the residence times recited in

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instant claim 5, for performing the Lee invention in a packed bed reactor. One of ordinary skill in the art would have been motivated to do this since it would have yielded different fat/oil products, as demonstrated in Xu et al. Moreover, studying the effect of flow rate in a packed bed reactor is deemed suitable for demonstrating the promising aspects of the use of Lipozyme TL IM for interesterification (Xu et al., page 561, second columns, first full paragraph). Varying the residence times also would have been a matter of routine experimentation. Thus, instant claim 5 is rendered obvious.

A holding of obviousness is clearly required.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN E. FERNANDEZ whose telephone number is (571)272-3444. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford/
Primary Examiner, Art Unit 1651

Susan E. Fernandez
Examiner
Art Unit 1651

sef